Section 2 Summary

JUL 24 2012

510(k) Summary of Safety and Effectiveness

Date: April 19, 2011

Submitter:
Medical Minds LLC
11491 78th. Ave
Allendale, MI 49401

Contact Person:
David Platt
Vice President of Quality and Regulatory
Medical Minds LLC
616-308-2859

Device: Trade Name: Compression Care Flight

Common/Usual Name: Compression Limb Sleeve Device

Classification Names: Compression Limb Sleeve

CFR Reference: 21CFR870.5800

Classification Name: Sleeve, Limb, Compressible

Product Code: JOW

Predicate Device: K061125 – DVTcare™ CA5

This predicate device submission was made by Doctor's Orders, Inc.

Device Description:

The Compression Care Flight system is a light weight, portable, prescriptive device that helps stimulate blood flow in the legs through the use of pneumatically controlled, single chamber leg cuff(s), actuated by an electronically controlled pump unit and solenoid valves. All pump control unit components are protectively housed in a plastic shell except the outer membrane switch (needed for user interface), 2 plastic quick disconnects for air tube connection, and an external power supply input jack. The option exists for the unit to be used in single leg or double leg modes.

The control unit is supplied with a non-serviceable, rechargeable battery, to allow user portability, and a power supply transformer for mains connection.

Intended Use:

The Compression Care Flight is a pneumatic compression device intended to be an easy to use, portable system that is prescribed by healthcare professionals, to help prevent the onset of DVT in patients, by stimulating blood flow in the legs (simulating muscle contractions). Furthermore, the unit can be used as an aid in the prophylaxis for DVT by persons traveling, or those expecting to be stationary for long periods of time (greater than 4 hours). This device can also be used to: aid in the prevention of DVT, enhance blood circulation, diminish post-operative pain and swelling, reduce wound healing time, and aid in the treatment and healing of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous and arterial insufficiency, and reduction of edema in the lower limbs.

Substantial Equivalence of Technological Characteristics:

The Compression Care Flight is similar to the predicate device listed above in the function and operating principles to achieve identical results. The Compression Care Flight offers greater treatment flexibility due to the portability, adjustable pressure, and cycle time capabilities. Our system uses a microprocessor controlled pump to deliver pressurized air (programmable up to 65 mmHg) to bladders that are attached to the patient's lower limbs, using a cycle of approximately 60 seconds / leg as prescribed by a healthcare provider. Each cycle consists of one inflation (fill time approximately 10-12 seconds) followed by deflation. The Compression Care Flight has the capability of allowing a healthcare professional the following feature adjustment options: pressure set point (programmable up to 65 mmHg), hold time (0 seconds, not adjustable), cycle time (60-75 seconds). The cycle time is the length of time for one complete cycle on one leg including fill time, exhaust, and idle time (relaxation).

The Compression Care Flight uses similar means for pressure delivery as the predicate device. Pressurized air is delivered by the pump to the leg cuffs via flexible, plastic air tubes connected to the plastic pump / control unit by locking, quick disconnect couplings. Like the DVT Care CA5, the Compression Care Flight leg cuffs are comprised of a single bladder PVC chambers encased in a soft Nylon material to increase patient comfort and compliance.

Like the DVT Care CA5, the microprocessor and pump units are powered by an internal battery supply and can be connected to the mains power supply for operation and recharging.

Non-Clinical Testing

Non-clinical validation including electrical safety and performance testing have shown that the Compression Care Flight has performance characteristics substantially equivalent to or superseding the listed predicate device. The Compression Care Flight has been validated by Medical Minds at a design validation level based on the requirements of IEC 60601-1. Additional bench testing has verified equivalent pressure delivery, cuff (garment) fill time, cycle time and system operation as the predicate device listed. Test reports can be found in Appendix 1.

Conclusion:

The Compression Care Flight is designed for the same intended use as the predicate device, the DVT Care CA5. This comparison of the specifications demonstrates the functional equivalence of the products. The differences discussed in this section do not raise new issues of safety and effectiveness. Verification and validation testing demonstrated that no adverse effects have been introduced by these differences.

Medical Minds LLC believes that the Compression Care Flight is as safe and effective and performs substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 24 2012

Medical Minds LLC
c/o Mr. David Platt
Vice President of Quality & Regulation
11491 78th Avenue
Allendale, MI 49401

Re: K121376
Trade/Device Name: Compression Care Flight
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: April 12, 2012
Received: May 8, 2012

Dear Mr. Platt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121376

Section 11 Indications for Use

Indications for Use

510(k) Number (if known): K121376

Device Name: Compression Care Flight

Indications For Use:

The Compression Care Flight is intended to be an easy to use, portable system that is prescribed by healthcare professionals, to help prevent the onset of DVT in patients, by stimulating blood flow in the legs (simulating muscle contractions). Furthermore, the unit can be used as an aid in the prophylaxis for DVT by persons traveling, or those expecting to be stationary for long periods of time (greater than 4 hours). This device can also be used to: aid in the prevention of DVT, enhance blood circulation, diminish post-operative pain and swelling, reduce wound healing time, and aid in the treatment and healing of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency, and reduction of edema in the lower limbs.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121376